



A Statistically-Based Method for Establishing NAFTA-Harmonized Tolerances



May 2005

Current Method

- Identify highest residue from a field trial data set
- “Round Up”
- Make different conclusions regarding appropriate level

Tolerance “Balancing Act”

- Balance probabilities associated with wrongly seizing a legally treated crop vs. probability of being incapable with a reasonable degree of surety of detecting illegal use
- **GOAL:**
 - Set tolerances at a level high enough so as to avoid seizing crops which were legally treated...*
 - ...but low enough such that residues from illegal use can be detected*

Charge to NAFTA Tolerance Harmonization Workgroup

- Develop a statistically-based, standard method for determining tolerance levels
 - Be scientifically defensible
 - Result in same level when applied to same/similar data sets

Participants

- USEPA/PMRA NAFTA Workgroup
- Observers
 - European Commission
 - European Food Safety Agency
 - California Department of Pesticide Regulation

Criteria for Methodology

- Any developed methodology should:
 - Be reasonably simple to use by non-statisticians (requiring only calculators or spreadsheets)
 - Aim to be reasonably-well accepted
 - Be based – as far as possible – on accepted statistical principles and methods
 - Incorporate information about sample size and variance
 - Consistent across data sets
 - Effectively accomplish appropriate “balancing”

Outcome

- A statistically-based, scientifically defensible methodology
 - Use common procedure universally
 - Encourage sharing of field trial data and increase opportunities for worksharing
 - Assure tolerances strike the appropriate balance
 - Reduce trade barriers

Milestones and Next Steps

- **Activities Completed**

- Goals established
- Available, published methodologies applicable to statistical analysis of field trial data investigated
- Alternative methodologies tested based on existing data sets
- Methodology developed, tested, and validated
- Standard operating procedures in use

- **Future Activities**

- **Dissemination of draft SOP for stakeholders' review and comment**
- **Develop statistical “white paper”**
- **Develop supplemental guidance on methods (e.g. for combining field trial data within crop groupings)**
- **Submission to NAFTA Executive Board for final comment/approval**

US EPA Upcoming Planned Outreach Efforts and Activities

- NAFTA Executive Board Meeting
 - **May 2-3** (Ottawa)
- USEPA Contractor Training
 - **May 9**
- PPDC Meeting
 - **May 11-12** (Arlington)
- Crop Life America
 - **May 20/24**
(Washington, D.C.)
- OECD Meeting
 - **June 6-10** (Paris)
- American Chemical Society National Meeting
 - **August, 2005** (Washington, D.C.)
- OECD Meeting
 - **November, 2005** (New Zealand)
- NAFTA/Stakeholder Meeting
 - **December, 2005** (U.S.)